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10/789,433	02/27/2004	Mark Thomas Muldoon	19596-0571 (45738-296417)	5696

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JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,433	MULDOON ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13, 15-17 and 20* is/are pending in the application.

4a) Of the above claim(s) *20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed October 31, 2007 has been entered. Claim 10 has been amended. Claims 1-9, 14 and 18-19 have been cancelled. Claim 20 is newly added. Claims 10-13 and 15-17 and SEQ ID NO:2 are under consideration in this office action.

Election/Restrictions

2. Newly submitted claim 20 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: SEQ ID NO: 3-6, 9-13 and 15-35 do not share physical and functional characteristics. The amino acid sequences constitute patentably distinct inventions which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each sequence comprises separate and distinct amino acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 20 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 10-16 under 35 U.S.C. 102(b) as being anticipated by Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413); and

b) The rejection of claims 10-18 under 35 U.S.C. 103(a) as being unpatentable over Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001) in view of Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10-13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

An assay for detecting a mammalian troponin molecule in animal feed the assay comprising: a) reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under

conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2.

Neither the specification nor originally presented claims provides support for reacting the animal feed with a ligand. Applicant did not point to support in the specification for reacting the animal feed with a ligand. Moreover, applicant failed to specifically point to the reaction of the animal feed with a ligand. Thus, there appears to be no teaching of an assay for detecting a mammalian troponin molecule in animal feed as claimed.

Applicant has pointed to pages page 3, lines 14-16 and page 5, lines 6-7 of the instant specification for support of the amendment drawn reacting the animal feed with a ligand. Page 3 recites detecting mammalian muscle proteins in a sample such as animal; while page 5 defines the term animal feed. However neither teaches reacting the animal feed with a ligand. Page 16, lines 25-26 of specification teach an embodiment involving a direct assay wherein sample is placed under conditions effective to cause any troponin molecules in the sample to become fixed on a substrate. Page 17, lines 20-25, teach a solid sample being subject to extraction procedures wherein the resultant supernatant is contacted with the ligand. The teaching of deriving a substance that reacts with the ligand is not equivalent to reacting the animal feed with a ligand. The animal feed itself can not bind to the ligand which is specific to

mammalian troponin molecules, not the animal feed. Thus it appears that the entire specification appears to fail to recite support for the newly recited step within the assay. Therefore, it appears that there is no support in the specification.

Applicants must specifically point to page and line number support for an assay for detecting a mammalian troponin molecule in animal feed the assay comprising: a) reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2 as recited by the newly added amendments. Therefore, the claims incorporate new matter and are accordingly rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10-13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to an assay for detecting a mammalian troponin molecule in animal feed the assay comprising: a) reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims encompass the reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2.

The unpredictability of the art and the state of the prior art

Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413); Sheng et al., teach assay for detecting a mammalian rabbit skeletal muscle the polypeptide troponin I (TnI) molecule in a lysate sample, by western blotting whereby the sample contains a rabbit fast skeletal monoclonal antibody ligand specific for troponin I having SEQ ID NO:2 to form a complex between the antibody and troponin I; and detecting the complex as a measure of the presence of troponin I Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001) teach immunological methods for detecting the porcine troponin I by ELISA using a monoclonal antibody or ligand for detecting porcine skeletal troponin I. Chen et al., teach detecting porcine sTnI in a sample sufficient to form a complex between the antibody ligand and the troponin. All of this underscores the criticality of providing working examples for reacting the troponin I with a ligand that is specific for the mammalian troponin molecule and not specific for an

avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule. There is no teaching of reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule.

Working examples

The specification teaches the suitability of reacting troponin I with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule. There are no immunological experiments provided which demonstrate that the claimed method is capable of creating a complex between the ligand and the animal sample. There is no teaching within the specification of reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex that meets the limitations of the claims in the manner instantly claimed.

Guidance in the specification

The specification provides insufficient guidance and objective evidence that reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions

sufficient is capable of forming a complex between the ligand and the mammalian troponin molecule. Therefore, the specification fails to enable the assay as claimed. The instant specification fails to provide any experiments that show that reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule.

At best, Page 16, lines 25-26 of specification teach an embodiment involving a direct assay wherein sample is placed under conditions effective to cause any troponin molecules in the sample to become fixed on a substrate. Page 17, lines 20-25, teach a solid sample being subject to extraction procedures wherein the resultant supernatant is contacted with the ligand, however this disclosure is not equivalent to guidance or objective evidence that an assay for detecting a mammalian troponin molecule in animal feed the assay comprising reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 2 is enabled. Therefore, the specification fails to enable an assay for detecting a mammalian troponin molecule in animal feed the assay

Level of skill in the art

The level of skill in the art is deemed to be high.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of reacting the animal feed with a ligand that is specific for the mammalian troponin molecule, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which are not commensurate in scope to the claims and the negative teachings in the prior art balanced only against the high skill level in the art, thus it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform assay of the claim as broadly written.

Accordingly, this would require undue experimentation given the fact that the specification is lacking in teachings.. Applicants' have provided no guidance to enable one of ordinary skill in the art as to how determine, without undue experimentation, an assay for detecting a mammalian troponin molecule in animal feed the assay comprising: a) reacting the animal feed with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the animal feed; and, wherein the ligand is an antibody produced by immunizing an animal with a peptide having an amino acid

sequence selected from the group consisting of SEQ ID NO: 2; therefore, one of skill in the art would have to locate *de novo* steps required for an assay for detecting a mammalian troponin molecule in animal feed.

Conclusion

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 28, 2008

MARK NAVARRO
PRIMARY EXAMINER